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09/938,334	08/23/2001	Joong Hyuck Auh	6181/OJ707	9995

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,334

Applicant(s)

Auh et al.

Examiner

Ralph Gitomer

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 7, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) 3-20, 22, and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 21, and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

Applicant's election with traverse of Group 1, claims 1, 2, 21, 23, in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the separate Groups do not warrant separate examination and search. This is not found persuasive because the Groups are separate and distinct inventions as described in the Restriction Requirement.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Asokan.

On page 5 of the present specification, the novelty of the invention is described as obtaining a sample of both plasma and hemocyte lysate from insects, and adding a chelating agent to chelate calcium ions during the following separation process.

Asokan (Developmental and Comparative Immunology) entitled
❖Activation of Prophenoloxidase in the Plasma and Haemocytes of
the Marine Mussel❖ teaches on page 2 column 1, phenoloxidase is
found in both haemocytes and plasma of insects and crustaceans.
5 It is known to employ EDTA anticoagulant in collecting samples.
On page 3 haemocyte lysate is prepared, purified and assayed. On
page 4, the effect of calcium activation at different
concentrations was assayed. On page 5 column 2, the enzyme has
been localized in both plasma and haemocytes of arthropods. On
10 page 10 column 1, calcium ions are known to be necessary for
activation of phenoloxidase.

Claims 1, 2, 21, 23 are rejected under 35 U.S.C. 102(b) as
being anticipated by Leonard.

15 Leonard (Insect Biochem) entitled ❖Studies on
Prophenoloxidase and Protease Activity of Blaberus craniifer
Haemocytes❖ teaches in the abstract, using EDTA as an
anticoagulant it was possible to isolate haemocytes from an
insect. A lysate contained prophenoloxidase which could be
20 activated by beta 1,3-glucans. This activation process was
dependent upon calcium concentration. On page 804 hemolymph was
prepared from insects in EDTA and purified. Plasma cannot be
collected without EDTA. On page 805, calcium was used to
activate compositions. On page 806 glucan concentrations
25 detected at -4 micrograms/ml are shown. On page 808 column 1,

employing EDTA is discussed with both hemocytes and hemolymph.

All the features of the claims are taught by the above references for the same function as claimed.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically
disclosed or described as set forth in section 102 of this title, if the
differences between the subject matter sought to be patented and the prior
art are such that the subject matter as a whole would have been obvious at
15 the time the invention was made to a person having ordinary skill in the
art to which said subject matter pertains. Patentability shall not be
negativated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a),
20 the examiner presumes that the subject matter of the various
claims was commonly owned at the time any inventions covered
therein were made absent any evidence to the contrary. Applicant
is advised of the obligation under 37 CFR 1.56 to point out the
inventor and invention dates of each claim that was not commonly
25 owned at the time a later invention was made in order for the
examiner to consider the applicability of 35 U.S.C. 103[®] and
potential 35 U.S.C. 102(f) or (g) prior art under 35
U.S.C. 103(a).

Claims 2, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Asokan in view of Ashida.

On page 7 of the present specification, the composition of the present invention enables detection of glucans as low as 20 pg/ml in the mixture of insect's plasma and hemocytes is what is considered to be the meaning of claim 2.

Asokan (Developmental and Comparative Immunology) entitled Activation of Prophenoloxidase in the Plasma and Haemocytes of the Marine Mussel teaches on page 2 column 1, phenoloxidase is found in both haemocytes and plasma of insects and crustaceans. It is known to employ EDTA anticoagulant in collecting samples. On page 3 haemocyte lysate is prepared, purified and assayed for phenoloxidase activity. On page 4, effect of calcium activation at different concentrations was assayed. On page 5 column 2, the enzyme has been localized in both plasma and haemocytes of arthropods. On page 10 column 1, calcium ions are known to be necessary for activation of phenoloxidase and are assayed at concentrations ranging from 0.01 to 10 mM.

Claim 2 differs from Asokan in that it specifies glucans are detected at 20 picograms per milliliter.

Ashida (4,970,152) entitled Reagents for Determining Peptidoglycan and Beta 1,3-Glucan teaches in Fig. 3, detecting glucan concentrations at 0.01 ng/ml. In column 5 to perform the purification more effectively, it is desirable to remove

previously the influence of cations such as calcium by adding a chelating agent such as EDTA. The fraction which specifically reacts with beta glucans can easily be obtained. In column 6 prior to the determination of glucans, it is necessary to add calcium ions which are removed from the reagent solution during the preparation of the fraction which specifically reacts with glucans, to the reaction solution.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the claimed composition as taught by both of the above references with a very low calcium ion concentration, and to then detect picogram/milliliter concentrations of glucans which is specifically taught by Ashida, because it would be likely the compositions of Asokan would also perform in the same manner because it is the same composition made for the same function.. No substantive difference is seen in the compositions taught by each of the references. And no criticality is seen in the selection of any specific particular concentration detected because the claims are directed to a composition only.

Claims 1, 2, 21, 23 are rejected under 35 U.S.C. § 112,
second paragraph, as being indefinite for failing to particularly
point out and distinctly claim the subject matter which applicant
regards as the invention. Each of the following applies in all
occurrences.

In claim 1(ii) line 2, ~~existing~~ may be more definite as
~~present~~. In claim 1(ii) ~~during a present separation process~~
lacks antecedent basis and no separation is seen as written. How
the fractions are obtained and what they contain is not set forth.
Claim 2 is not understood as presented. It is directed to a
composition but no components are seen. Further, what the
minimum is of is not recited. Claim 23 is indefinite regarding
how a composition is characterized is not in what may be
performed with it. And the activity of what is not described.

The title of the invention is not aptly descriptive. A new
title is required that is clearly indicative of the invention to
which the claims are directed.

This application does not contain an abstract of the
disclosure as required by 37 CFR 1.72(b). An abstract on a
separate sheet is required.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Tanaka (5,266,461) teaches determining glucans.

Ashida (5,585,248) teaches preparing prophenoloxidase.

5 Katsumi (6,274,565) teaches detecting glucans.

Ashida (Eur J Biochem) teaches maintaining prophenoloxidase in nonactivated state during collection.

Brehelin (Insect Biochem) teaches insect hemolymph.

Brivio (Comp Biochem Physiol) teaches on page 282, hemolymph was
10 collected in EDTA.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner
15 can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 872-
20 9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing

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Center for more information.

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Ralph Gitomer
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